REMARKS/ARGUMENTS

All examined claims were rejected as being obvious over the teachings of Sirhan '375 in view of Toner '039. Such rejections are traversed in part and overcome in part.

Applicants generally agree with the Examiner's characterization of the Sirhan '375 patent. The '375 patent does disclose a stent which carries a therapeutic capable agent which is at least partially covered by a rate controlling element. A release of the therapeutic capable agent is intended to inhibit restenosis in patients having vascular disease.

Applicants strongly disagree, however, with the Examiner's assertion that Toner '039 would teach one skilled in the art to substitute pimecrolimus for the therapeutic capable agents taught by Sirhan.

Toner '039 specifically teaches that pimecrolimus is useful as a "hydration inhibitor" which is intended to control the release of a beneficial agent which is loaded on to the device in a base layer of a polymeric material. As taught in paragraph 13 of the '039 publication, the hydration layer is intended to control "the delivery of the beneficial agent from the layer of the polymeric material."

While Toner '039 does teach that in some cases the hydration agent may also be a second beneficial agent, nowhere does Toner teach or suggest that the pimecrolimus or other hydration agent would ever be needed or associated with a further rate-controlling element or component as required by claims 1 and 20 in the present application.

Both claims 1 and 20 in the present application require that the therapeutic capable agent comprising pimecrolimus be at least partially covered by a rate-controlling element. Both claims 1 and 20 have now been amended to clarify that it is the rate controlling membrane which controls the release rate of the pimecrolimus.

The teachings of Toner '039 are contrary to the method and structure of the present invention. Toner '039 specifically teaches that the pimecrolimus and other hydration elements provide the function of controlling the release rate of a primary beneficial agent which is incorporated in the polymeric material. See, for example, paragraph 56 in the '039 publication. Thus, Toner hardly teaches or suggests providing a separate rate controlling element to control

the rate of pimecrolimus release since Toner teaches that pimecrolimus in fact provides the rate controlling function.

CONCLUSION

For these reasons, Applicants believe that all claims pending in the application are allowable and request that the application be passed to issue at an early date.

If for any reason the Examiner believes that the telephone conference would in any way expedite prosecution of the subjection application, the Examiner is invited to telephone the undersigned at 650-326-2400.

Respectfully submitted,

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